through their participation in the research of the Smokeless Tobacco Research Council. *See* section II.D.1., above.

Second, the evidence also shows that smokeless tobacco manufacturers manipulate the delivery of nicotine to consumers. In addition to testing the nicotine deliveries of UST products, FDA also tested the nicotine deliveries of smokeless tobacco manufactured by Conwood Co. and Swisher International. This testing showed that like UST, these companies also graduate their nicotine deliveries in a manner that promotes tolerance and addiction. Another company, Pinkerton Tobacco Co., also controls nicotine deliveries through the use of pouches for its starter products. *See* section II.D.2.a., above.

This evidence of (1) knowledge of nicotine's pharmacological effects and uses and (2) manipulation of nicotine deliveries in a manner that encourages tolerance and addiction thus applies to the major smokeless tobacco manufacturers. The evidence is sufficient to establish that these manufacturers intend their products to affect the structure and function of the body.[1101]

2. One comment states that FDA fails to distinguish between different smokeless tobacco products, namely moist snuff and chewing tobacco. The comment states that FDA is required to establish independently that each product is intended to affect the structure and function of the body. The comment also claims that FDA does not have any information about categories of smokeless tobacco other than moist snuff.

FDA believes that there is no basis in the record for treating chewing tobacco differently than moist snuff. Studies demonstrate that both snuff and chewing tobacco

[1101] FDA's authority to assert jurisdiction over a class of similar products, such as smokeless tobacco, rather than assert jurisdiction company by company is further discussed in section II.F., below.

products rapidly deliver equal or even greater amounts of nicotine to the bloodstream than the amounts delivered by cigarettes.[1102] These studies also show that both snuff and chewing tobacco produce similar peak blood levels of nicotine. Moreover, as described in sections II.A. and II.B., above, the evidence shows that all smokeless tobacco—including both moist snuff and chewing tobacco—is addictive and is used by consumers for pharmacological effects. Because the pharmacological effects of moist snuff and chewing tobacco are essentially the same, the two products should be treated the same.

In addition, moist snuff and chewing tobacco are generally manufactured by the same companies. The manufacturers do not argue that a "Chinese wall" exists at these companies that separates their moist snuff operations from their chewing tobacco operations. Therefore, having established that these manufacturers intend that their moist snuff products affect the structure and function of the body, FDA may properly presume that these manufacturers have the same intent when manufacturing another product (in this case, chewing tobacco) that causes the same pharmacological effects.

[1102] Department of Health and Human Services, Office on Smoking and Health, *Report of the Advisory Committee to the Surgeon General, The Health Consequences of Using Smokeless Tobacco* (Washington DC: DHHS, 1986), at 143-167. *See* AR (Vol. 128 Ref. 1591).

Benowitz N, Porchet H, Sheiner L, et al. Nicotine absorption and cardiovascular effects with smokeless tobacco use: comparison with cigarettes and nicotine gum, *Clinical Pharmacology and Therapeutics* 1988;44:23-28. *See* AR (Vol. 12 Ref. 134).

There is also evidence that tobacco manufacturers deliberately use high-nicotine tobaccos in chewing tobacco. A document submitted to the record by the tobacco industry states that chewing tobaccos utilize dark, air-cured tobacco types that are "cultivated in a manner conducive to heavy body and high nicotine content." Tobacco, in *Encyclopedia of Chemical Technology,* eds., Kirk RE, Othmer DF (New York: The Interscience Encyclopedia Inc.), 14:244. See AR (Vol. 535 Ref. 96, vol. IV.B).

E. THE "INTENDED USE" OF A PRODUCT IS NOT DETERMINED ONLY ON THE BASIS OF PROMOTIONAL CLAIMS

Sections II.A.-D., above, described the evidence before the Agency establishing that cigarettes and smokeless tobacco are intended to affect the structure or function of the body, and briefly discussed FDA's legal authority to consider evidence of foreseeable pharmacological effects and uses, actual consumer use, and the statements, research, and actions of manufacturers. In this section, FDA responds to comments on the legal basis for considering these groups of evidence.

Several comments agreed with the analysis of the intended use of cigarettes and smokeless tobacco set forth in the Jurisdictional Analysis. The tobacco industry, however, submitted several comments in opposition to the Agency's analysis of the intended use of cigarettes and smokeless tobacco, including the joint comments submitted by the cigarette manufacturers and the joint comment submitted by the smokeless tobacco manufacturers. The Agency received additional comments that made arguments similar to those of the tobacco industry.

The principal contention of the tobacco industry is that whether a product is "intended" to affect the structure or any function of the body may be determined "only" on the basis of the claims made by the manufacturer to the consumer in connection with the sale and distribution of the product. According to the tobacco industry, because they do not overtly promote the pharmacological use of cigarettes and smokeless tobacco, their products are not "intended" to affect the structure or function of the body under the Act and FDA is therefore powerless to regulate them.

The tobacco industry's argument cannot be correct. Their contention is contrary to the plain language of the Act, FDA's regulations, judicial precedent, and the Agency's long-standing interpretation of the Act. If adopted, this interpretation would allow any drug manufacturer or importer to avoid FDA jurisdiction simply by not making certain types of claims—even for products with powerful pharmacological effects.

As discussed more fully below, the Agency finds that the arguments made by the tobacco industry are unpersuasive and that the determination of whether a product is "intended" to affect the structure or function of the body may be based not only on the promotional claims of the manufacturer, but also on other objective evidence of intended use. This other objective evidence of intent may include evidence of the foreseeable pharmacological effects and uses of the product, evidence of how consumers actually use the product, and evidence of the manufacturers' statements, research, and actions that reveal the product's intended uses.

Moreover, the Agency disagrees with the premise of the manufacturers' argument—namely, that consideration of promotional claims shows that cigarettes and smokeless tobacco are not drugs or devices under the Act. As discussed in section II.E.2., below, the Agency agrees with the comments that argue that the manufacturers' advertisements do in fact support the Agency's conclusion that cigarettes and smokeless tobacco have intended pharmacological uses.

1. The "Intended Use" of a Product May Be Established on the Basis of All Relevant Objective Evidence of Intent

As noted in section II.A.1., above, in determining whether an article is "intended" to affect the structure or function of the body, "the FDA is not bound by the

manufacturer's subjective claims of intent," but rather can find actual intent "on the basis of objective evidence." *National Nutritional Foods Ass'n (NNFA) v. Mathews*, 557 F.2d 325, 334 (2d Cir. 1977). That is, the Agency determines a product's intended use objectively by evaluating all of the relevant evidence in the record from the perspective of a reasonable fact finder. *See* 21 CFR 201.128, 801.4. In determining intended use, the Agency may "examine a wide range of evidence." *United States v. Two Plastic Drums . . . Black Currant Oil*, 761 F. Supp. 70, 72 (C.D. Ill. 1991), *aff'd*, 984 F.2d 814 (7th Cir. 1993).

Although promotional claims are relevant objective evidence of intent, the statute, the Agency's regulations, and judicial and administrative precedent do not restrict FDA to consideration of only the manufacturer's promotional claims.[1103] The Act has not been—and should not be—interpreted in a manner that would permit manufacturers of products that contain known drug ingredients and have known pharmacological uses to circumvent FDA regulation by deliberately avoiding overt drug claims. When a product contains a known drug ingredient like nicotine, the Agency may properly look beyond the manufacturer's promotional claims to other objective evidence of the intended uses of the product. This ability to look beyond and behind promotional claims that deliberately deny,

[1103] The Agency agrees that the claims made by the manufacturer in advertising and promotional materials can be relevant evidence of the manufacturer's intent. Indeed, in many cases, no further evidence of intended use is needed. In the case of a typical approved drug, the manufacturer will forthrightly promote the pharmacological uses to which the drug should be put, the drug will in fact produce the promoted pharmacological effects, and consumers will use the drug for its promoted purposes. Promotional claims may be implied as well as express. For example, the Act provides that, in determining whether labeling or advertising is misleading, the Agency must consider the representations "suggested" as well as "made" in the labeling or advertising. Section 201(n), 21 U.S.C. 321(n). Similarly, courts have found an intent to affect the structure or function of the body based on commercial names that "suggest" drug uses. *See, e.g., United States v. Storage Spaces Designated Nos. "8" and "49,"* 777 F.2d 1363, 1366 (9th Cir. 1985), *cert. denied*, 479 U.S. 1086 (1987).

or are silent about, the actual intended uses of a product is critical to FDA's capacity to protect the public health under the Act.

a. The Plain Meaning of the Statute Authorizes FDA To Consider All Evidence of Intent

"When interpreting a statute, [the courts] look first and foremost to its text." *United States v. Alvarez-Sanchez*, 114 S. Ct. 1599, 1603 (1994). The pertinent provision from the statutory definition of "drug," section 201(g)(1)(C) of the Act, 21 U.S.C. 321 (g)(1)(C), states: "The term 'drug' means . . . articles (other than food) *intended* to affect the structure or any function of the body of man or other animals" (emphasis added). The corresponding device definition, section 201(h)(3), states:

> The term "device" . . . means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar related article, including any component, part, or accessory, which is . . . *intended* to affect the structure or any function of the body of man or other animals.

21 U.S.C. 321(h)(3) (emphasis added).

These definitions do not dictate that the "intended" effects or uses of an article be established in any particular manner or by any specific type of evidence. Similarly, they do not preclude the use of any type of evidence to make the pertinent showing. The statutory language is plain on its face and permits FDA to consider any relevant evidence in determining what uses are "intended."

The broad statutory language cannot be reconciled with the narrow view that "only" claims made to the consumer in connection with the sale of a product are relevant in determining the "intended" uses of a product. If Congress had meant to so limit the evidence that could be used to determine intended uses, it would have used a phrase such

as "promoted to," "labeled to," "advertised to," or "represented to" in lieu of "intended to" in the definitional sections. Indeed, Congress explicitly refers to representations, labeling, and advertising in other sections of the Act. *See* section 201(n) of the Act, 21 U.S.C. 321(n) (whether a drug or device is misbranded depends, among other factors, on the manufacturer's "representations" made in "labeling or advertising"); section 502(a), 21 U.S.C. 352(a) (a drug or device is misbranded if, among other bases, its "labeling" is false or misleading); section 502(n), 21 U.S.C. 352(n) (a drug is misbranded, among other bases, unless its "advertisements and other descriptive printed matter" contain certain true statements). That Congress did not expressly restrict the Agency to promotional claims means that evidence of intended use need not be limited to promotional claims. As the Supreme Court recently observed, "it is generally presumed that Congress acts intentionally and purposely when it includes particular language in one section of a statute but omits it in another." *Keene Corp. v. United States*, 508 U.S. 200, 208 (1993).[1104]

The tobacco industry's position also conflicts with the canon of statutory construction that words used by Congress, unless otherwise defined, will be interpreted as taking their ordinary meaning. *See, e.g., Smith v. United States*, 113 S. Ct. 2050, 2054 (1993); *Chevron v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 860 (1984). Contrary to the manufacturers' view, the ordinary and widely accepted meanings of "intend" are significantly broader than those of "promote."

[1104] Similarly, the legislative history of the Act cited by the tobacco industry fails to support the tobacco industry's position. Nowhere in that history are any authoritative statements that intended use may be established only by promotional claims. *See* S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935) *reprinted in* 3 Legislative History 660; S. Rep. No. 493, 73d Cong., 2d Sess. (1934) *reprinted in* 2 Legislative History 720; H. Rep. No. 853, 94th Cong., 2d Sess. (1976) *reprinted in* An Analytical Legislative History of the Medical Device Amendments of 1976, appendix III. Section II.E.3.a. provides additional discussion of the legislative history.

II.E.1.

As discussed in section II.C.1., above, one ordinary meaning of "intend" is to have in mind or design for a particular purpose. Consistent with this meaning, the Agency interprets "intended uses" to include those uses that are "in the mind" of or planned by the manufacturer or for which the manufacturer designs the product. The evidence that is relevant to establish the uses that the manufacturer "has in mind" or for which the manufacturer has designed the product is plainly substantially broader than evidence of only promotional claims. It may include, for instance, evidence of the internal statements, research, and actions of the manufacturer's senior scientists and officials.

As discussed in section II.A.1., above, "intend" in its ordinary legal usage also encompasses readily foreseeable consequences. As the Supreme Court recognized nearly a century ago, "[t]he law presumes that every man intends the legitimate consequences of his own acts." *Agnew v. United States*, 165 U.S. 36, 53 (1897). Consistent with this meaning, "intended uses" include the foreseeable pharmacological effects and uses of the product. The evidence that is relevant to establish these effects and uses is substantially broader than evidence of promotional claims. It may include, for instance, evidence of a product's widely known pharmacological effects and uses.[1105]

[1105] Additional demonstration that the intended use of a product may be determined based on evidence other than the express claims of the manufacturer is provided by the Dietary Supplement Health and Education Act (DSHEA), Pub. L. No. 103-417, 108 Stat. 4325. Before the passage of the DSHEA, dietary ingredients and dietary supplements that did not have taste, aroma, or nutritive value (and thus were not foods, *see Nutrilab, Inc. v. Schweiker*, 713 F.2d 335, 337 (7th Cir. 1983)) could be classified as "drugs" if, among other things, the manufacturer made claims that the product would affect the structure or any function of the body. In the DSHEA, Congress created an exception to section 201(g)(1)(C). Under this exception, a dietary supplement or dietary ingredient "for which a truthful and not misleading statement is made . . . is not a drug under clause (C) *solely* because the label or the labeling contains such a statement." 21 U.S.C. 321(g)(1)(C) (emphasis added). The fact that Congress expressly provided that an intent to affect the structure and function of the body cannot be established "solely" on the basis of promotional claims plainly implies that other evidence beyond promotional claims can be relevant evidence of intent.

II.E.1.

The tobacco industry's view that the "intended use" of a product may be determined "only" by examining promotional claims thus cannot be squared with the plain language of the statute. Congress did not provide that FDA may regulate only products "promoted" to affect the structure or function of the body. Rather, Congress provided that FDA may regulate products "intended" to affect the structure or function of the body. A wide range of evidence can be probative of a manufacturer's intent.

b. FDA's Regulations Authorize FDA To Consider All Evidence of Intent

Consistent with the plain language of the statute, FDA's regulations defining "intended use" for drugs and devices, 21 CFR 201.128 (drugs) and 21 CFR 801.4 (devices), clearly contemplate that FDA may consider a range of evidence that extends well beyond the claims made by manufacturers in connection with the sale and distribution of their products. Even if the statute were not plain on its face, the Agency has broad discretion to interpret the Act in a reasonable manner consistent with its public health purposes. *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798 (1969).

These regulations, which have been in effect for four decades, define the "intended uses" of drugs and devices that must be included in the product's labeling. Although they do not specifically define the statutory terms "drug" or "device," the Agency routinely uses the regulations to interpret the statutory intent requirement. *See* section II.A.1.,

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Indeed, in *United States v. Ten Cartons, More or Less, of an Article . . . Ener-B Vitamin B-12*, 72 F.3d 285, 287 (2d Cir. 1995), the Second Circuit Court of Appeals stated that this language clearly implies that a dietary supplement can be a drug under this section for reasons other than the claims made for it, such as its method of intake. Thus, the court found that Ener-B, which was a vitamin B-12 supplement designed to be applied to the inside of the nose and absorbed into the bloodstream through the nasal mucous membranes, was a drug. *Id.*

above. Indeed, the comments of the tobacco industry assert that these regulations have "authoritatively . . . defined" intended use under the Act.[1106]

The regulation that describes the intended use of drugs provides:

> *The words "intended use" or words of similar import . . . refer to the objective intent of the persons legally responsible for the labeling of drugs.* The intent is determined by *such persons' expressions* or may be shown by *the circumstances surrounding the distribution of the article.* This objective intent may, for example, be shown by labeling claims, advertising matter, or *oral or written statements* by such persons or their representatives. It may be shown by *the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.* The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But *if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it,* he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

21 CFR 201.128 (emphasis added). Section 801.4, which defines "intended use" for devices, is essentially the same except for the use of the word "device" in lieu of "drug" and the reference to regulations governing devices.

The italicized language shows that the "intended uses" of a product may be determined not only by "labeling claims" and "advertising matter," but also by other "expressions" and "oral or written statements" made by persons legally responsible for the

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[1106] Joint Comment of the Cigarette Manufacturers, Comment (Jan. 2, 1996), vol. II, at 6; *see* AR (Vol. 535 Ref. 96); *accord* Joint Comment of the Smokeless Tobacco Manufacturers, Comment (Jan. 2, 1996) at 102 ("[t]he regulation describing FDA's understanding of 'intended use' is consistent with the congressional purpose behind the drug definition"). *See* AR (Vol. 526 Ref. 95).